TÜV

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60006172 0001

Report No.: 30392044 001

Manufacturer:
CardioDynamics
6175 Nancy Ridge Drive
San Diego, CA 92121
USA

Scope:
Design, Development, Production, Servicing, and Distribution of Hemodynamic Monitoring Systems

Products: see attachment

Replaces Approval, Registration No.: HD 9811719 01

Date of Expiry: 21.10.2008

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 22.10.2003

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle TÜV Rheinland

Notified Body

Dipl.-Ing. D. Meier

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE